

## REMARKS

Reconsideration of the patentability of the above referenced patent application is solicited in view of the above amendments and the following comments

The examiner's comments regarding the claims language have been considered and the claims suitably amended. It is believed that the claims are now in good form for United States practice and that, therefore, the rejections under 35 USC 112 should be withdrawn. All of the amendments to the current claims are formal and editorial in nature in that they insure that the claims of this application conform to United States practice. These amendments have no relation to the patentability of the instant claims over the state of the prior art. The instant amended claims as well as the claims as previously presented (prior to this amendment) are equally patentably distinct from the state of the prior art. Therefore, these amendments do not raise any issue of prosecution history estoppel.

Note should be taken that two new claims have been added. Claim 23 is an independent claim that is similar to claim 10 but is somewhat broader in some aspects. This new claim is fully supported by the instant application as originally filed.

Note too that new claim 24 conforms to good United States practice. New claim 24 is directed to the nature of the spherical bodies that comprise an essential element of the instant claimed prosthesis. In the original specification and in the presently amended claims, these spherical bodies are characterized as being, among other things, rigid and not substantially deformable. The material from which these bodies is a rigid, non-oxidizing material that is not elastically deformable in the sense that this term is used in the Baumgartner references. By way of contrast, the Baumgartner references characterize their "support members" as being an "elastic plastic", "elastically deformable under stress", "elastic support structure" (in the abstract), and "elastically deformable support members" (column 1 of the specification). These support members are illustrated by polyurethane (see column 2), which is known to be an elastic, rubbery

kind of material. Further, the materials disclosed in the Baumgartner reference are indeed oxidizable since they are elastic plastic.

Claim 24 has been introduced to insure that the composition and nature of the spherical bodies of this invention do not inadvertently overlap with the support members defined by the Baumgartner reference. Although there is no *in haek verba* support for the feature of claim 24, that the instant spherical bodies are not elastically deformable, the fact that they are stated to be rigid and not oxidizable, makes them not deformable in the sense that the term is used by Baumgartner. This should be sufficient support for the negative limitation now set forth in new claim 24. Entry and allowance of this claim are therefore solicited.

The examiner's indication of the allowability of claims 13-16 is acknowledged. Rewriting these claims in independent form is respectfully deferred pending completion of the prosecution of this application.

In the outstanding office action, the examiner has rejected the patentability of claims 10, 11, 17, 19, 20, 21 and 22 as being anticipated by the disclosure of the cited Baumgartner '797 patent. The examiner's assertions are amply set out on pages 4 and 5 of the office action. This rejection is respectfully traversed. The examiner has characterized the support material of the '797 patent as rigid. That is simply not true and, in fact, is contrary to the requirements of the reference. The reference specifically calls for the support material to be elastically deformable. That is not rigid. The instant claims call for the spherical bodies to be rigid and not oxidizable. The material of the spherical bodies of this invention is not an elastically deformable material (such as an elastic plastic) as this term is used in the reference. Therefore, the rejection under 35 USC 102 cannot be sustained and must be withdrawn.

There is also a rejection of claims 10, 11, 12, 17, 19 and 20 as being anticipated by the disclosure of the Baumgartner '644 reference. This reference is directed to a one piece, whole disc prosthesis. It is not directed to a nucleus prosthesis as are the instant

claims. In this reference, the prosthetic material, which may be a titanium alloy, is cut parallel to its plane so that a plurality of leaf spring members are produced. Clearly, the resiliency provided by these leaf spring members is reminiscent of the annulus of the disc rather than the nucleus of the disc.

The examiner has stated that this reference discloses an intervertebral nucleus prosthesis. That is simply not so. It discloses a one piece **disc** prosthesis. The examiner has stated that this reference discloses a nucleus prosthesis that consists of at least one spherical body 9. It does not. The area designated as 9 of this reference is directed to a fixation **zone** that does not have leaf spring elements. It is not a spherical body as claimed herein (see Figs. 3-6 and 8 of the reference).

The '644 patent does not disclose a cage containing at least one spherical body that is the prosthetic nucleus assembly. It does not even disclose a cage feature of any kind in a prosthetic nucleus. The '644 patent does not disclose any rotatable elements, that is it does not disclose any balls. The rotation referred to in this reference is about a tangential generatrix of the circular fixation zone. The referenced circular fixation zone is not a rotatable ball.

It is clear that the elastic plastic support members of the '797 patent are not the same feature as the fixation zones of the '644 patent. The fact that the '644 patent refers to titanium and a material from which the one piece whole disc prosthesis can be made has no relation to the '797 patent reference to polyurethane rubber for its support members. In the '644 patent, the entire prosthesis can be made of titanium alloy. In the '797 patent only a small portion of the prosthesis is disclosed to be made of polyurethane rubber balls.

In the '797 patent, the support members are elastic plastic materials that are stuffed into the cavity from which the nucleus has been removed. These members are not necessarily all the same size nor all the same material, nor all the same shape, but they all are elastically deformable. By way of contrast, the spherical bodies of the instant

invention are structurally limited to the plane of a cage in which they are fixed. The diameter of these bodies is consistent with the thickness of the nucleus material that would have been in the disc had it not become damaged. The bodies of this invention do not pile one atop the other as disclosed in the '797 reference, nor are they interleaved spring like members as disclosed in the '644 reference. The instant claims clearly require the rigid, non-oxidizable spherical bodies of this invention to be limited in their ability to translate out of the plane of the cage in which they reside. The plane of the cage is consistent with the plane of the removed nucleus. Thus, the spherical bodies of this invention are fixed in the cage so that they can move in the plane of the "nucleus" but cannot move, to any appreciable extent, out of the plane of the "nucleus/cage"

It is pointed out that the '797 reference discloses implanting at least three elastically deformable support members individually inserted into the cavity (that is the cavity left when the damaged nucleus was removed) and individually positioned relative to each other. By way of contrast, in the instant claimed invention, the spherical bodies are assembled with the cage in a substantially fixed structure, that is the spherical bodies are pre-assembled in the cage, and this unit is inserted into the cavity that was left when the damaged nucleus was removed.

As briefly noted above, the '797 reference discloses mounting support members in a "pearl necklace" arrangement or within a series of "bags, each of which carries one support member (see figures 6-8). These disclosed embodiments do not describe the instant prosthesis wherein the spherical bodies are mounted in a cage with portions of the bodies protruding from the respective lateral sides of the cage. In the reference, the support members are mounted on a linking element 20, 22, and are not disclosed to be non-displaceably mounted within a cage, while permitting the bodies to be freely rotatable in the plane of the cage, as required by the instant claims.

It is therefore clear that neither the '797 nor the '644 references anticipate, nor even render obvious, the instant invention as defined in claims 10 and 23.

The examiner's comments regarding the relationship between the disclosure of the Baumgartner '797 reference and the remaining dependent claims is similarly unrelated to the patentability of the instant claims as they all require the essential spherical body to be rigid and non-oxidizable. That is, the instant claimed spherical bodies not an oxidizable elastic plastic like polyurethane rubber. The rejection that has been entered on this basis should be withdrawn.

Note should be taken of the fact that instant claim 10 requires that the spherical bodies be maintained in a cage and that the cage holds the spherical bodies such that they can move substantially only in the plane of the cage and not, to any appreciable extent, in a plane transverse to the plane of the cage. There is no such feature disclosed in the '797 or '644 references. In fact, the disclosure of the '797 reference is quite to the contrary. It permits and even encourages support members to pile over each other in many transverse planes and not to be fixed in the lateral plane of a cage within the cavity that had previously been occupied by the damaged nucleus. Further, claim 10 requires that the spherical body(s) protrude from both lateral sides of the cage while they are held in the cage in a rotatable manner. There is no disclosure of such a structure in the '797 reference. The examiner's reliance on the disclosure of figures 6-8 is misplaced. These figures do not show rigid, non-oxidizable spherical bodies protruding from both lateral sides of a cage such that the spherical body(s) can only move in the plane of the cage and not, to any appreciable extent, transverse to that lateral plane, as is required by the instant claims.

The '797 reference describes enveloping its support members in a bag 10. That bag is not a cage as that term is used and defined in the instant application. The reference bag merely separates the support members from the annulus. It does not hold the support members in a fixed lateral relationship as does the cage of the instant invention. It does not provide for the support members to protrude from any portion of the bag. It is pointed out that the cage of the instant invention preferably has a casing or border that is preferably made of titanium. This casing maintains the spherical bodies within the casing. An important embodiment of this invention provides for a mass of material, such

as polyethylene, to be disposed within the casing in the cage. One could then say that it is the polyethylene that is held in a desired shape and configuration by the casing and the rigid, non-oxidizable spherical bodies that are held in their appropriate place and relationship by the polyethylene. The fact that the spherical bodies are not substantially deformable, as is required in the reference, is important because the instant spherical bodies are intended to be rotatable in the plane of the cage. The fact that they are rigid enables them to rotate without substantial deformation.

As to claim 11, the examiner asserts that it discloses a cage that is curved in a plane and symmetrical to a transverse center plane. The examiner cited figures 6-8 as support for this contention. It is urged that the examiner reconsider her reliance on these figures. These figures show that several support members can be assembled like a string of pearls. There is no disclosure in the reference of such a "string of pearls" being maintained in a mass that is retained within a casing to make up a cage from which the support members protrude on both lateral sides. There is no disclosure in the '797 reference of a cage or any other structure, comprising the instant rigid, spherical bodies, that is curved substantially symmetrically to a transverse center plane.

As to claim 14, the examiner asserts that the reference discloses a cage with an isosceles trapezoidal shape. She points to lines 43-46 of column 4. There is no such disclosure. At the place indicated by the examiner, the reference states that the bag can be adapted to any desired shape of the cavity (defined by the annulus). This has no relationship to the cross sectional shape of applicants' cage. In fact, since there is no cage disclosed in the reference, there is also no disclosure of any cross sectional shape or area of such a cage.

As to claim 17, there is no disclosure in the '797 reference of a nucleus prosthesis having a trapezoidal cross section, certainly no disclosure of an isosceles trapezoidal cross section prosthesis. In the reference, the elastic support members are not fixed in specific positions as is required by the instant claims. Rather, the support members of the reference are free to move about the space of the cavity so that, taken as a whole, the

mass of support members does not keep any specific shape. Note that in the instant claim, the rigid spherical bodies are required to extend on both sides of the cage to an imaginary horizontal plane outside the plane of the cage. There is no such disclosure in this reference.

Referring to claim 20, the prosthesis disclosed in the '797 reference does not have a spherical cap protruding from both sides of the a cage. The reference' varying the diameter of some of the support members is not sufficient to set the height of the protrusion from the cage. In the instant invention, the casing about the cage and the cage thickness are both related to the height of the spherical bodies so that the height of the protrusion of the balls from the cages is not variable and is such as to substantially replace the height of the damaged nucleus that is being replaced.

As to claims 21 and 22, the method claims, it will be clear that the '797 reference inserts its support members individually, one at a time into a cavity until the cavity is filled. By contrast, the instant prosthesis is assembled with all of the balls fixed in their places in the cage and the whole prosthesis is then introduced into the cavity. There is no disclosure in the '797 patent that suggests the instant claimed process.

In the outstanding action, the examiner has rejected claims 10, 11 and 20 as being anticipated by the disclosure of the Ahrens Uwe '975 reference. This rejection is respectfully traversed. This reference discloses a prosthesis for replacement of joints such that it is only suited to use with round structures such as knees, hips or shoulders. This reference describes providing a rolling means for bone tips inside a recess. Thus, the prosthesis must be thin and dome shaped. In contrast, the instant prosthesis is principally planar, not dome shaped. The very thin dome shaped prosthesis of this reference requires means to fix the large balls protruding from the prosthesis in the form of spherical caps. These spherical caps have a height that is much greater than 10% of the diameter of the balls, which is what is disclosed and claimed herein.

The '975 reference discloses a prosthesis that is curved in several planes. By contrast, the instant invention has a curvature only within the plane of the prosthesis. Thus claim 11, is not met by this reference.

It should be noted that instant claim 20 requires the presence of protruding spherical caps that have a height that is about one tenth of the diameter of the spherical body. The spherical caps that are disclosed in this reference are much larger than one tenth of the ball diameter. This limitation is important because it enables the balls to be fixed in lateral place, be rotatable in that plane and prevent movement transverse to the plane of the prosthesis. Thus this reference is not antithetical to the patentability of claims 10, 11 and 20.

The examiner has rejected the patentability of claims 10 and 11 as being anticipated by the disclosure of the cited European 577 179 A1 reference. This rejection is respectfully traversed. This reference discloses a prosthesis where the balls are so mounted that they can only rotate in one direction because they are fixed on a connection element that enables them to rotate only about the connecting element. This reference does not disclose any cage that holds the balls in a fixed position but allows them freedom of rotation in all directions as is required in the instant claims. The reference does not show a structure where at least one ball is fixedly held by a cage such that it can only move within the plane of the cage and cannot move to any appreciable extent in a direction that is transverse to the plane of the cage. The reference does not show fixing the ball in a cage so that a small portion of the ball protrudes above and below, respectively, the plane of the cage whereby enabling the ball to maintain the spacing between adjacent vertebra and to take up the stress of movement of the vertebra.

It is therefore urged that this reference is not antithetical to the patentability of the instant claimed invention.



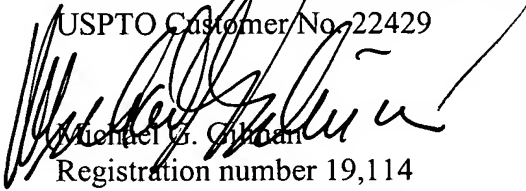
The examiner has commented about requiring section lines in figure 8. However, as is clear from the specification, figure 8 is a side view. Therefore section lines would not be appropriate

The examiner has commented about black shading in the drawing. Applicants are not aware of any such shading. The thick arrows in the drawing show movement of the vertebra and are not shading at all. It is urged that the examiner be more explicit in her observation. Applicants will make every effort to accommodate any drawing changes that may be necessary. It is uncertain, but perhaps the examiner is concerned with what appears to be shading in Fig. 1. No shading was intended. It is perhaps the fault of the reproduction of the drawing that makes it appear as if there is black shading. If that is the case, applicants are prepared to submit a clearer drawing corresponding to Fig. 1 that will not have the appearance of black shading. The examiner's comments are solicited.

In view of the above amendments and comments, it is believed that the claims of this application all define a patentable invention and they should be allowed.

It is believed that the instant claims are now in condition for allowance and such action is solicited.

Respectfully submitted,  
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